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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/989,796   | 11/20/2001  | Michael Y. Zhang     | ACSC 59931 (1987D)  | 1816             |
| 24201  | 7590        | 05/03/2007           | EXAMINER            |                  |
| FULWIDER PATTON LLP<br>HOWARD HUGHES CENTER<br>6060 CENTER DRIVE, TENTH FLOOR<br>LOS ANGELES, CA 90045 |             |                      | BUI, VY Q           |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 3734                |                  |
|  |             |                      | MAIL DATE           | DELIVERY MODE    |
|  |             |                      | 05/03/2007          | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

09/989,796

Applicant(s)

ZHANG ET AL.

Examiner

Vy Q. Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26 and 28-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26 and 28-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION*****Specification***

The amendment filed 2/14/2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

Claim 1: "the inflated configuration outer diameter at the inflation pressure at the substantially ambient temperature as part of a catheter system". There is no disclosure in the specification about the outer diameter at the inflation pressure at the substantially ambient temperature as part of a catheter system. The original specification is silent regarding the temperature of the balloon as part of a catheter system. Without a specific disclosure of the original specification, there is no way one can determine if "the inflated configuration outer diameter at the inflation pressure as part of a catheter system" is measured when the balloon is at the same ambient temperature as that of the balloon after the heat treatment process.

Applicant is required to explain the subject matters to have a support in the specification or cancel the new matter in the reply to this Office Action.

The shrinkage percentage is not clearly defined in the specification and thus the claimed shrinkage percentage in claim 1 is not clearly defined either. It would be proper to consider that the present claimed invention therefore is not defined over WANG et al. (5,556,383) as presented below.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26, 28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by WANG et al. (5,556,383).

Notice that as mentioned above, the shrinkage percentage is not clearly defined in the specification and thus the claimed shrinkage percentage in claim 1 is not clearly defined either. Therefore, Wang reference is still applicable to the claimed invention. Wang (for example 1 and table 1) discloses a polymeric balloon having a radial shrinkage less than 6% and a length of about 2cm. It appears that at least the condition (temperature of the balloon as a part of a catheter system) for determining the shrinkage percentage in this present invention is not clearly defined in the specification.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 30-33, 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over WANG et al. (5,556,383).

As to claims 30-32, WANG (example 1 and table 1) discloses a polymeric balloon having substantial all structural limitation as recited in the claims, except for the axial growth is less than 6% or 10%. However, WANG discloses radial shrinkage less than 6% in a radial direction and the material of the balloon is substantially homogenous, therefore, it would be reasonable to expect the growth percentage in a same order to the radial shrinkage or less than 6% or 10%.

As to claim 33, WANG (example 1 and table 1) discloses a polymeric balloon of pebax (col. 5, lines 51) having substantial all structural limitation as recited in the claims, except for the balloon is made at least in part of a polyurethane. However, pebax and polyurethane are well-known low compliant polymeric materials suitable for manufacturing balloon in a balloon catheter. It would have been obvious to one of ordinary skill in the art at the time of the invention to have polyurethane as a material to make WANG balloon, as this configuration would guarantee a low compliant balloon with low shrinkage percentage.

As to claims 34-35, WANG (example 1 and table 1) discloses a polymeric balloon of pebax (col. 5, lines 51) having substantial all structural limitation as recited in the claims, except for length of the balloon as recited in the claims. However, the length of a balloon is mostly dependent on the length of a stenosis, which varies dependent on an individual patient. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to specify the length of the balloon as recited in the claims so that different lengths of the balloons are available for different individual patients.

As to claims 36-37, WANG (example 1 and table 1) discloses a polymeric balloon of pebax (col. 5, lines 51) having substantial all structural limitation as recited in the claims, except for the balloon thickness in the range as claimed. However, it would have been obvious to one

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of ordinary skill in the art at the time of the invention to make WANG balloon having a thickness in the range as recited in the claims for other applications requiring balloons with bigger sizes.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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04/30/2007

Vy Q. Bui  
Primary Examiner  
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